January 30, 2004

SENATE BILL No. 111

DIGEST OF SB 111 (Updated January 28, 2004 4:56 pm - DI 104)

Citations Affected: IC 25-26.

Synopsis: Drug regimen protocols. Expands protocols concerning the adjustment of a patient's drug regimen to nursing homes. Sets forth requirements for protocols used in nursing homes. Requires quarterly review of protocols.

Effective: July 1, 2004.

Dillon

January 6, 2004, read first time and referred to Committee on Health and Provider Services.
January 29, 2004, amended, reported favorably — Do Pass.

January 30, 2004

Second Regular Session 113th General Assembly (2004)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2003 Regular Session of the General Assembly.

SENATE BILL No. 111

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 25-26-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]:

Chapter 16.5. Drug Regimens in Health Facilities

Sec. 1. This chapter applies to a health facility licensed under IC 16-28.

Sec. 2. (a) As used in this chapter, "attending physician" means a physician licensed under IC 25-22.5 who is responsible for the ongoing health care of an individual who resides in a health facility.

(b) The medical director of a health facility to which the individual is admitted may not serve as the individual's attending physician unless the medical director meets the requirements set forth in subsection (a).

Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning the adjustment of a patient's drug regimen as allowed under this

chapter by a pharmacist licensed under this article.

Sec. 4. As used in this chapter, "therapeutic alternative" means a drug product that:

(1) has a different chemical structure from;

(2) is of the same pharmacological or therapeutic class as; and

(3) usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses as;

another drug.

Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug; or

(4) adds a drug to the treatment regimen.

Sec. 6. At the time an individual is admitted to a health facility that has adopted a protocol under this chapter, the individual's attending physician shall signify in writing in the form and manner prescribed by the health facility whether the protocol applies in the care and treatment of the individual.

Sec. 7. (a) A pharmacist may adjust the drug therapy regimen of the individual under:

(1) the written authorization of the individual's attending physician under section 6 of this chapter;

(2) the health facility's protocols; and

(3) this chapter.

(b) The pharmacist shall review the appropriate medical records of the individual to determine whether the attending physician has authorized the use of a specific protocol before the pharmacist adjusts the individual's drug therapy regimen.

(c) Notwithstanding subsection (a), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the attending physician to receive approval to begin the protocol. The pharmacist shall document the authorization of the attending physician to use the protocol immediately in the individual's medical record.

Sec. 8. If a health facility elects to implement, revise, or renew a protocol under this chapter, the health facility shall establish a drug regimen review committee consisting of:

(1) the health facility's medical director;

(2) the health facility's director of nursing; and

(3) a consulting pharmacist licensed under this article;

for the implementation, revision, or renewal of a protocol.

Sec. 9. Except for the addition or deletion of authorized physicians and pharmacists, a modification to a written protocol requires the initiation of a new protocol.

Sec. 10. (a) A protocol of a health facility developed under this chapter must be:

(1) based on clinical considerations; and

(2) reviewed by the health facility's drug regimen committee at least quarterly.

(b) A protocol of a health facility developed under this chapter may not:

(1) prohibit the attending physician from approving only specific parts of a protocol; or

(2) provide for an adjustment to an individual's drug regimen for the sole purpose of achieving a higher reimbursement for the substituted drug therapy than what would have been received for the original drug therapy ordered by the attending physician.

Sec. 11. A protocol developed under this chapter must include the following:

(1) The identification of:

(A) the individual whose drug regimen may be adjusted;

(B) the attending physician who is delegating the authority to adjust an individual's drug regimen; and

(C) the pharmacist who is authorized to adjust the individual's drug regimen.

(2) The attending physician's diagnosis of the individual's:

(A) condition; or

(B) disease state;

whose drug regimen may be adjusted.

(3) A statement regarding:

(A) the types and:

(i) categories; or

(ii) therapeutic classifications;

of medication, including the specific therapeutic alternatives that may be substituted for a drug prescribed by a physician;

(B) the minimum and maximum dosage levels within the types and:

(i) categories; or

(ii) therapeutic classifications;

of medications described in clause (A);

(C) the dosage forms;

(D) the frequency of administration;

(E) the route of administration;

(F) the duration of the administration of the drug regimen and any adjustment to the drug regimen; and

(G) exceptions to the application of the drug regimen or the adjustment to the drug regimen;

for which the pharmacist may adjust the individual's drug regimen.

(4) A requirement that:

(A) the individual's medical records be available to both the individual's attending physician and the pharmacist; and

(B) the procedures performed by the pharmacist relate to a disease or condition for which the patient has been under the attending physician's medical care.

Sec. 12. A protocol developed under this chapter that is implemented for a Medicaid recipient must comply with any statutes, regulations, and procedures under the state Medicaid program relating to the preferred drug list established under IC 12-15-35-28.

Sec. 13. If a protocol developed under this chapter allows a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order.

Sec. 14. This chapter does not allow a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol under this chapter.

Sec. 15. The individual's attending physician:

(1) shall review a protocol approved for a patient of the physician at least quarterly; and

(2) may at any time modify or cancel a protocol by entering the modification or cancellation in the individual's medical record.

Sec. 16. (a) Documentation of protocols must be maintained in a current, consistent, and readily retrievable manner.

(b) After making an adjustment to an individual's drug regimen,

the pharmacist shall notify the individual's attending physician of the adjustment not later than one (1) business day after the adjustment is made.

Sec. 17. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.

(b) This chapter does not make any other licensed health care provider liable for the actions of a pharmacist carried out under this section.

Sec. 18. A pharmacist who violates this chapter is subject to discipline under IC 25-1-9.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 111, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 1, delete lines 1 through 17, begin a new paragraph and insert:

"SECTION 1. IC 25-26-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]:

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(b) The medical director of a health facility to which the individual is admitted may not serve as the individual's attending physician unless the medical director meets the requirements set forth in subsection (a).

Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning the adjustment of a patient's drug regimen as allowed under this chapter by a pharmacist licensed under this article.

Sec. 4. As used in this chapter, "therapeutic alternative" means a drug product that:

(1) has a different chemical structure from;

(2) is of the same pharmacological or therapeutic class as; and

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Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

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that has adopted a protocol under this chapter, the individual's attending physician shall signify in writing in the form and manner prescribed by the health facility whether the protocol applies in the care and treatment of the individual.

Sec. 7. (a) A pharmacist may adjust the drug therapy regimen of the individual under:

(1) the written authorization of the individual's attending physician under section 6 of this chapter;

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(b) The pharmacist shall review the appropriate medical records of the individual to determine whether the attending physician has authorized the use of a specific protocol before the pharmacist adjusts the individual's drug therapy regimen.

(c) Notwithstanding subsection (a), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the attending physician to receive approval to begin the protocol. The pharmacist shall document the authorization of the attending physician to use the protocol immediately in the individual's medical record.

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(1) the health facility's medical director;

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(1) prohibit the attending physician from approving only specific parts of a protocol; or

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(A) condition; or

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Sec. 17. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.

(b) This chapter does not make any other licensed health care provider liable for the actions of a pharmacist carried out under this section.

Sec. 18. A pharmacist who violates this chapter is subject to discipline under IC 25-1-9.".

Delete pages 2 through 3.

and when so amended that said bill do pass.

(Reference is to SB 111 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.